

**Bone Marrow Transplantation (BMT) Services**  
**Discussion Items – Working Document**

<b>Section 3. Requirements for approval for proposing to initiate a BMT service: On-site availability of services</b>		
<b>Current Standards:</b>	<b>Issues Identified During Public Hearing</b>	<b>Proposed Modifications/Changes</b>
<p><b>Section 3. (3)(b)</b></p> <p>An applicant proposing to initiate either an adult or pediatric bone marrow transplantation service shall demonstrate that the licensed hospital site at which the transplants will be offered provides each of the following staff, services, and programs, as of the date an application is submitted to the department:</p> <p>Continuous <u>on-site</u> availability, either immediate or on-call, of CT scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medical services.</p> <p><b>Section 3. (3)(h)</b></p> <p>A histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics, or an equivalent organization, either <u>on-site</u> or through written agreement.</p>	<p>The requirement to have specific support services on-site may be unreasonable. Due to space considerations at many medical centers, certain support and ambulatory services have been moved out of the main hospital facility. Hence, the requirements for on-site availability of various laboratory, pathology and blood services, and support services, like radiation therapy, should be required to be available on-site, or immediately adjacent to the proposed hospital site.</p>	

Current Standards:	Issues Identified During Public Hearing	Proposed Modifications/Changes
<p data-bbox="153 272 352 305"><b>Section 3. (3)(j)</b></p> <p data-bbox="205 337 688 500">A clinical chemistry lab with the capability to monitor antibiotic and antineoplastic drug levels, available either <u>on-site</u> or through other arrangements that assure adequate availability.</p> <p data-bbox="153 532 352 565"><b>Section 3. (3)(l)</b></p> <p data-bbox="205 597 688 727">Continuous availability of anatomic and clinical pathology and laboratory services, including clinical chemistry, and immuno-suppressive drug monitoring.</p> <p data-bbox="153 760 373 792"><b>Section 3. (3)(m)</b></p> <p data-bbox="205 824 646 889">Continuous availability of red cells, platelets, and other blood components.</p> <p data-bbox="153 922 321 954"><b>Section 3. (7)</b></p> <p data-bbox="205 987 688 1149">An applicant shall provide on-site megavoltage radiation therapy services with a nominal beam energy of at least 6 MEV, including the capability to perform total body irradiation.</p>		

Section 3. Requirements for approval for proposing to initiate a BMT service: Restriction on number of BMT services		
Current Standards:	Issues Identified During Public Hearing	Proposed Modifications/Changes
<p><b>Section 3. (5)(a)</b></p> <p>An applicant shall demonstrate that the number of existing adult bone marrow transplantation services in the planning area identified in Section 2 (1)(s)(u)(i)? does not exceed (3) adult bone marrow transplantation services and that approval of the proposed application will not result in the total number of adult bone marrow transplantation services exceeding three (3) in the planning area.</p> <p><b>Section 3. (5)(b)</b></p> <p>An applicant shall demonstrate that the number of existing pediatric bone marrow transplantation services does not exceed two (2) pediatric bone marrow transplantation services in planning area one identified in Section 2 (1)(s)(u)(ii)(A) or one (1) pediatric bone marrow transplantation service in planning area</p>	<p>The current standards restrict the number of bone marrow transplantation centers in the state of Michigan to three (3)<sup>1</sup> adult bone marrow transplant centers. There is no need-based criterion to support the number.</p> <p>There is no access to adult BMT services on the western part of the state since the existing adult BMT services are located in South East Michigan. The patients have to travel 120 miles to get BMT services</p> <p>Oncologists at large cancer centers without a BMT program must refer patients to outside centers and outside physicians for this treatment. This interrupts their continuity of care and negatively impacts the strong doctor-patient relationships that are established. Referrals elsewhere also require significant re-testing and re-staging. These tests add substantial costs to the health care system and impose</p>	

**Comment:** Section 2 (1)(u)(i) Planning area means : for an adult bone marrow transplantation service, the state of Michigan.

**Comment:** 2 (1)(u) (ii)(A) Planning area means; planning area one that includes the counties in health service areas 1,2,5, and 6, and the following counties in health service area 7: Alcona, Cheboygan, Crawford, Montmorency, Oscoda, Otsego, and Presque Isle; or

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<p><u>two</u> identified in Section 2 (1)(s)(u)(ii)(B) and that approval of the proposed application will not result in the total number of pediatric bone marrow transplantation services exceeding the need for each specific pediatric planning area.</p>	<p>unnecessary hardships for these patients.</p> <p>Establishing and maintaining a BMT service require a huge investment of both manpower and financial resources. The existing stem cell transplantation centers are operating under capacity. Increasing the number of centers in Southeast Michigan would result in a costly duplication of services that are already available.</p>	
Section 3. Requirements for approval for applicants proposing to initiate a BMT service: Minimum volume requirements		
Current Standards:	Issues Identified During Public Hearing	Proposed Modifications/Changes
<p><b>Section 3. (6)(a)</b></p> <p>An applicant proposing to initiate an adult bone marrow transplantation service that will perform only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at least 10 allogeneic transplant procedures will be performed in the third 12-months of operation. An applicant proposing to initiate an adult bone marrow transplantation service that will perform <u>only autologous procedures</u></p>	<p>The CON requirement (10 transplants per year) for a program only performing autologous transplants is greater than the requirement (5 transplants per year) contained in the proposed 3<sup>rd</sup> edition of the FACT_JACIE accreditation standards. The state requirements should not be more stringent than the FACT-JACIE requirements. Upon finalization of the 3<sup>rd</sup> edition of the FACT-JACIE accreditation standards, the CON Review Standards</p>	

**Comment:** 2 (1)(u)(ii) (B) planning area two that includes the counties in health service areas 3, 4, and 8, and the following counties in health service area 7: Antrim, Benzie, Charlevoix, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, and Wexford.

Current Standards:	Issues Identified During Public Hearing	Proposed Modifications/Changes
<p><u>shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.</u></p> <p><b>Section 3. (6)(b)</b></p> <p>An applicant proposing to initiate a pediatric bone marrow transplantation service that will perform only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at least 10 allogeneic transplant procedures will be performed in the third 12-months of operation. An applicant proposing to initiate a pediatric bone marrow transplantation service that will perform <u>only autologous procedures shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.</u></p>	<p>should be revised to be consistent with them.</p>          <p>In Section 3 of the CON standards, there is no discussion of a combined adult and pediatric BMT program. The implication is that such programs represent two (2) separate entities, each of which must meet separate volume requirements (i.e., 10 annually for the adult service, and 10</p>	

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<p><b>Section 3. (10)(b)(c)</b></p> <p>For purposes of subsection (10), “existing bone marrow transplantation service” means a service that meets all of the following:</p> <ul style="list-style-type: none"> <li>(i) currently is and has been performing, for at least 3 years, the types of transplants (allogeneic or autologous; adult or pediatric)</li> <li>(ii) proposed to be performed by the applicant.</li> <li>(iii) Performed at least 15 pediatric allogeneic transplants or 40 adult allogeneic transplants in the most</li> </ul>	<p>annually for the pediatric service). The 2<sup>nd</sup> edition FACT standards specifically address combined adult and pediatric programs and require an annual volume of four (4) adult patients and (4) pediatric patients. The proposed 3<sup>rd</sup> edition FACT-JACIE standards will require five (5) from each patient population. The CON requirements should acknowledge combined adult and pediatric BMT programs and adjust the minimum volume requirements to match the FACT_JACIE standards.</p> <p>The minimum volume requirements for the existing program are excessively high and far exceed any applicable accreditation standards. Patient volumes consistent with FACT-JACIE accreditation requirements should be sufficient for an existing program to provide the consulting service required in the CON standards.</p>	

<p><b>Current Standards:</b></p> <p>(iv) recent 12-month period prior to the date an application is submitted to the Department.</p> <p>(v) Currently is certified by the National Marrow Donor Program and is located in the United States.</p> <p><b>Section 3. (10)(b)(d)</b></p> <p>An applicant shall document that the existing bone marrow transplantation service meets the requirements of subsection (c).</p>	<p><b>Issues Identified During Public Hearing</b></p>	<p><b>Proposed Modifications/Changes</b></p>
<p><b>Section 6. Project delivery requirements – terms of approval for all applicants: Accrediting Organizations’ name changes</b></p>		
<p><b>Current Standards:</b></p> <p><b>Section 6. (1)(i)(C)</b></p> <p>A processing and cryopreservation laboratory that meets the standards of the <u>Foundation for Accreditation of Hematopoietic Cell Therapy (FAHCT)</u> or an equivalent organization.</p> <p><b>Section 6. (1)(xii)</b></p> <p>A pediatric BMT service shall maintain membership status in either the <u>Pediatric</u></p>	<p><b>Issues Identified During Public Hearing</b></p> <p>The Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) is now called the Foundation for the Accreditation of Cellular Therapy (FACT).</p> <p>The Pediatric Oncology Group (POG) and the Children’s Cancer Group (CCG) have</p>	<p><b>Proposed Modifications/Changes</b></p>

[illegible]



Section 6. Project delivery requirements – terms of approval for all applicants: Minimum volume requirements		
Current Standards:	Issues Identified During Public Hearing	Proposed Modifications/Changes
<p><b>Section 6. (1)(xiv)(d)(i)(A)</b></p> <p>An adult BMT service that performs only allogeneic transplants, or both allogeneic and autologous transplants, shall perform at least 10 allogeneic transplants in the third 12-months of operation. <u>If an adult service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation.</u> After the third 12-months of operation, an applicant shall perform at least 30 adult transplants in any 36-month consecutive period, with no fewer than 5 allogeneic in any 12-month period, beginning with the third 12-months of operation, and thereafter.</p> <p><b>Section 6. (1)(xiv)(d)(i)(B)</b></p> <p>A pediatric bone marrow transplantation service that performs only allogeneic transplants, or both allogeneic and autologous transplants, shall perform at least 10 allogeneic transplants in the third 12-months of operation. <u>If a pediatric service performs only</u></p>	<p>The CON requirement (10 transplants per year) for a program only performing autologous transplants is greater than the requirement (5 transplants per year) contained in the proposed 3<sup>rd</sup> edition of the FACT_JACIE accreditation standards. The state requirements should not be more stringent than the FACT-JACIE requirements. Upon finalization of the 3<sup>rd</sup> edition of the FACT-JACIE accreditation standards, the CON Review Standards should be revised to be consistent with them.</p>	

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<p><u>autologous transplants, the service shall perform at least 10 autologous transplants</u> in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 pediatric transplants in any 36-month consecutive period, with no fewer than 5 allogeneic transplants in any 12-month period, beginning with the third 12-months of operation, and thereafter.</p>		